DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Minimally Invasive Devices, LLC
% Mr. Michael H. Southworth, RAC
Principal & Senior Consultant
Southworth & Associates, LLC
1035 Waldo Way
Twinsburg, OH 44087

JUL 27 2015

Re: K080613
Trade/Device Name: Clear-Vu™ System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCT, GCJ
Dated (Date on orig SE ltr): October 28, 2008
Received (Date on orig SE ltr): October 30, 2008

Dear Mr. Southworth,

This letter corrects our substantially equivalent letter of November 6, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K080613

Device Name: Clear Vu System

Indications for Use: Clear-Vu is a single-use, disposable laparoscopic accessory device that is intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080613

510(k) Summary of Safety and Effectiveness

Clear-Vu System
Minimally Invasive Devices, LLC

NOV – 6 2008

510(k) Submitter	Minimally Invasive Devices, LLC 1275 Kinnear Road Columbus, Ohio 43212
Contact Person	Wayne L. Poll, MD, Chairman *Phone:* (614) 580-2022 *Fax:* (614) 889-7630 *E-mail:* waynepoll@hotmail.com
Date Prepared	Revised October 28, 2008
Device Name	*Proprietary Name:* Clear-Vu System *Common Name:* endoscope lens cleaning and defogging device *Classification Name:* "accessory, endoscope," a class II device in accordance with 21 CFR § 876.1500
Intended Use	The Clear-Vu System is a single-use, disposable laparoscopic accessory device intended to facilitate intra-operative defogging and cleaning of the lens of a laparoscope during minimally-invasive surgery while maintaining visualization of the surgical site.
Device Description	The Clear-Vu System consists of a multi-lumen sheath assembly mounted on the shaft of the laparoscope, which connects to the existing CO_2 insufflation circuit to defog the laparoscope lens and divert surgical debris, and connects to the existing surgical irrigation system to clean the lens via saline flush.
Substantial Equivalence	The Clear–Vu System is substantially equivalent in terms of safety and effectiveness to the following predicate devices: 1. Defogging Heated Endoscopic Lens Protector / K062779 New Wave Surgical Corp. 2. Endo-Scrub® 2 / K982594 Xomed, Inc. 3. SeeClear™ Laparoscopic Smoke Evacuation System/510(k) Exempt JLJ Medical Devices International, LLC
Technological Comparison	The Clear-Vu System is substantially equivalent to the cited predicate devices in terms of intended use, and the technological differences are not significant relative to the safety or effectiveness of the new device.
Performance Testing-Bench	The device was subjected to simulated use testing to demonstrate its effectiveness in a surgical environment simulation chamber.
Performance Testing-Animal	The device was subjected to preclinical animal testing to demonstrate its effectiveness in a porcine model.